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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61M 5/48

A1

(11) International Publication Number: WO 00/06233

(43) International Publication Date: 10 February 2000 (10.02.00)

(21) International Application Number: PCT/US99/17262

(22) International Filing Date: 29 July 1999 (29.07.99)

(30) Priority Data:
60/094,998 31 July 1998 (31.07.98) US

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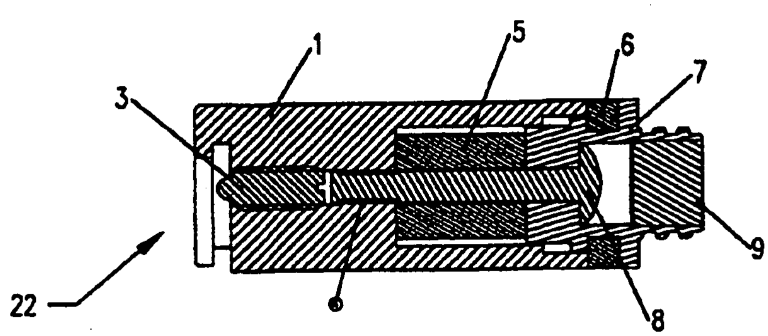
(81) Designated States: CN, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
*With international search report.*
*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: PRESSURE CONTROL SYSTEMS FOR MEDICAL INJECTORS AND SYRINGES USED THEREWITH




(57) Abstract

The present invention provides a pressure control system for an injector. The pressure control system includes a compliant piston or piston extension member that connects to the plunger of an injector-actuated syringe to prevent pressure overshoots when, for example, a closed or blocked fluid delivery pathway is encountered during an injection procedure.

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Description

# PRESSURE CONTROL SYSTEMS FOR MEDICAL INJECTORS AND SYRINGES USED THEREWITH

## Field Of The Invention

The present invention relates generally to medical injectors and syringes used therewith and, more particularly, to pressure control systems for injectors.

## Background Of The Invention

A number of powered injectors and injector-actuated syringes for use in medical procedures such as angiography, computed tomography (CT), ultrasound and magnetic resonance imaging (MRI) have been developed. For example, U.S. Patent No. 4,006,736 discloses an apparatus for injecting fluid into the vascular system of a human being or an animal. Likewise, U.S. Patent No. 4,677,980 discloses an angiographic injector including a rotating turret for housing two angiographic syringes in readiness for injection. Furthermore, U.S. Patent No. 5,383,858 discloses a front-loading injector and a syringe mountable thereon for injection procedures. The disclosures and drawings of U.S. Patent Nos. 4,006,736, 4,677,980 and 5,383,858 are hereby incorporated by reference.

Syringe-based injection systems are susceptible to maximum pressures that are higher than the desired programmed pressure when the fluid delivery path is closed or becomes blocked during an injection procedure. Fluid delivery paths can become closed or blocked for any number of reasons, including a closed stopcock or kinked tubing along the fluid path.

The programmed maximum pressure may be exceeded in the syringe due to the rapid rise of the fluid pressure in closed or blocked fluid delivery paths. In normal, open fluid path injection procedures, the control systems of conventional injectors are able to detect when the programmed maximum pressure is achieved and take control steps to decrease the injection speed to prevent pressure overshoots. However, the control systems are unable to deactivate or reverse the injector motor without inducing large and undesirable pressure fluctuations in the syringe and associated disposables. Therefore, during a normal injection, the control systems slow the injection as much as possible by terminating the current to the motor at a rapid controlled rate, thereby avoiding the large pressure fluctuations.

Unfortunately, these conventional control systems are unable to manage the problem of higher maximum pressures experienced during a closed or blocked fluid path injection.

In addition, powered injectors typically need to accommodate syringes having varying stiffness properties. For example, powered injectors may use both plastic and glass syringes, while utilizing the same pressure control algorithm.

## Summary Of The Invention

The present invention provides pressure control systems that control pressure overshoots in injector-actuated syringes and associated disposables caused by, for example, closed or blocked fluid delivery paths.

Further, the present invention provides pressure control systems for injectors that accommodate syringes having different stiffness properties, such as plastic and glass syringes.

According to a first aspect of the present invention, a pressure control system lowers pressure overshoots in syringes and associated disposables during an inadvertent closed or blocked fluid path injection.

According to a second aspect of the present invention, a pressure control system allows an injector to accommodate syringes having varying stiffness properties, while not increasing pressure overshoots during closed or blocked fluid path injections. For example, the pressure control system allows an injector to accommodate both plastic and glass syringes, while utilizing the same pressure control algorithm.

According to a third aspect of the present invention, a pressure control system correlates stiffness characteristics of one configuration of syringe to those of a different syringe. Therefore, the pressure control system is able to accurately control pressure overshoots

Figures 5a-5c are various views of the urethane spring of the pressure control system.

Figures 6a-6c are various views of the foam filler ring of the pressure control system.

Figures 7a-7c are various views of the plug of the pressure control system.

Figures 8a and 8b are various views of a syringe usable with the preferred embodiment of the pressure control system of the present invention.

Detailed Description Of The Invention

When rapid pressure rises occur in injector-actuated syringes and associated disposables, such as during a closed or blocked fluid path injection, the maximum pressure overshoots are a direct function of (1) the kinetic energy associated with the injection speed and pressure, and (2) the stiffness of the injector system and syringe.

The kinetic energy generated during these abnormal blocked fluid path injections is converted into potential energy as the movement of the injector piston decreases and comes to a stop. The kinetic energy is converted to potential energy by storing the energy in the form of pressure and deflection of the system and the syringe.

incurred during an inadvertent closed fluid path injection on all suitable syringe types.

In one embodiment, the pressure control system comprises a compliant injector piston that engages a plunger on an injector-actuated syringe.

In another embodiment, the pressure control system comprises a compliant piston extension member that is connected to a conventional injector piston and a plunger on an injector-actuated syringe.

The present invention, along with further aspects and attendant advantages, will best be understood by reference to the following detailed description taken in conjunction with the accompanying drawings.

## Brief Description Of The Drawings

Figure 1 is an exploded view of a preferred embodiment of the pressure control system of the present invention.

Figure 2 is a cross-sectional view of the pressure control system shown in Figure 1.

Figures 3a-3d are various views of the body of the pressure control system.

Figures 4a-4e are various views of the threaded tip of the pressure control system.

The syringe stiffness is typically designed by material choice and wall thickness to meet a certain pressure rating. The injector's mechanics typically adjust for or add compliance or increased deflections under loads to decrease the pressure in the syringe by storing more potential energy in terms of deflection and less in the form of pressure. Adding a spring in the mechanics (e.g., in the piston or in the form of a piston extension) with a controlled spring constant will store potential energy in the spring and decrease the maximum pressure for that system during a blocked fluid path injection.

Turning now to the drawings, a preferred embodiment of the pressure control system 20 of the present invention includes a compliant piston extension 22 (which may be delivered in a sealed, plastic package 10) compromised of the following parts as described below.

Urethane Spring (5)

As best shown in Figures 1, 2 and 5a-5c, a Shore 95A urethane spring 5 is preferably utilized in the compliant piston extension 22 to store the potential energy generated during the blocked fluid path injection. A standard steel coil spring could also be used, but the urethane spring 5 is preferred due to the large spring constants required, coupled with the fact that a large deflection could possibly exceed the stress limit of the steel used in a coil spring.

Body (1)

As best shown in Figures 1, 2 and 3a-3d, the body 1 of the compliant piston extension 22 houses the urethane spring 5, guides the threaded tip (see below) and incorporates a mechanism 1a, including a slot, for attaching the body 1 to the piston of the injector. In an additional embodiment, a bayonet connection, as shown and described in U.S. Patent No. 4,677,980, may be used to interconnect the body 1 to the piston.

The body 1 is preferably made from Delrin®, which has good mechanical strength and impact resistance, and a low coefficient of friction. Delrin® can be easily cleaned because contrast fluid does not adhere to its surface.

Threaded Tip (7)

As best shown in Figures 1, 2 and 4a-4d, the threaded tip 7 transfers the syringe load to the urethane spring 5 and includes threads which directly interface with the syringe plunger. In alternate embodiments, attachment mechanisms other than threads can be used to interconnect the syringe plunger and the tip 7. For example, a bayonet connection, as shown and described in U.S. Patent No. 4,677,980, may be used to interconnect the syringe plunger and the tip 7.

The threaded tip 7 preferably is made from Delrin® for ease of syringe attachment and cleaning, and for its low wear properties.

Foam Filler Ring (6)

As best shown in Figures 1, 2 and 6a-6c, the foam (or elastomeric) filler ring 6 resists fluid entry into the spring area and acts as a low-force collapsible zone during the injection. The foam ring 6 also prevents foreign matter from inhibiting deflection during an injection.

Carriage Bolt (8)

As shown in Figures 1 and 2, due to its square-neck design, the carriage bolt 8 holds the components of the compliant piston extension 22 together while at the same time preventing the threaded tip 7 from rotating relative to the body 1 when connecting the syringe thereto. The threads of the carriage bolt 8 are also preferably "loctited" to the body 1 via helicoil 4 to prevent rotation.

In alternate embodiments, fasteners other then the carriage bolt 8 could be used. For example, a stud could be used to accomplish substantially the same function as the bolt 8.

Plug (9)

As best shown in Figures 1, 2 and 7a-7c, the plug 9 covers the head of the carriage bolt 8, stiffens the threaded tip 7, and prevents foreign matter from inhibiting deflection during an injection.

Stubby Plunger (3)

As shown in Figures 1 and 2, the stubby plunger 3 helps retain the compliant piston extension 22 on the injector piston. The plunger 3 seats into a corresponding detent (not shown) in the injector piston and prevents unwanted movement of the compliant extension 22 on the piston during injector head positioning.

Syringe (30)

As shown in Figures 8a and 8b, a syringe 30 may be used with the compliant piston extension 22 of the present invention. The syringe 30 includes a plunger 32 disposed within a cartridge body 34. The front end 36 of the cartridge body 34 is enclosed by luer lock lids 38, 40, a gasket 42 and a lid holder 44. The rear end 46 of the cartridge body 34 is enclosed by a flange member 48.

As shown, the syringe plunger 32 is internally threaded to mate with external threads on the piston 22. In other embodiments, the syringe plunger 32 could include other attachment mechanisms for interconnecting the syringe plunger 32 and the piston 22. For example, as shown in U.S. Patent No. 4,677,980, the syringe plunger 32 may include hook or lug members (not shown) extending rearward therefrom for connection to a flange member extending from the piston 22.

## EXAMPLE

The preferred embodiment of the compliant piston extension 22 of the present invention is specifically designed to reduce the set pressure overshoot in a 100 ml glass syringe during a blocked fluid path injection. Specifically, the pressure overshoot was required to be reduced to at least the same pressure level experienced by a 100 ml plastic syringe.

The 100 ml glass syringe was measured to be 28% stiffer than the 100 ml plastic syringe. This 28% stiffness difference was the main cause for the higher pressure overshoots on injectors using the 100 ml glass syringe. Therefore, the compliant piston extension 22 (which was used in conjunction with the 100 ml glass syringe during an injection) incorporated a built-in stiffness constant to make the 100 ml glass syringe appear to the injector to be as stiff as or less stiff than the 100 ml plastic syringe. The stiffness constant or spring constant of the compliant piston extension 22 was calculated from the following relationship of springs in series:

$$1/K_{Plastic} = 1/K_{Glass} + 1/K_{Extension}$$

The urethane spring 5 for this design performed within the range of 2065 lb./in to 6384 lb./in. The high end of the range was determined from the above equation and the measured stiffness of the syringes. The low end was determined from the high pressure specification for the injector divided by the deflection available in the extension.

In the preferred embodiment described above, the pressure control system 20 has been described in terms of a piston extension 22 that connects to the piston of an injector. However, it is specifically contemplated that the pressure control system 20 and the piston extension 22 can be integrated into an injector piston that is operably associated with a drive mechanism, such as a drive motor and associated gearing, of the injector.

It should be appreciated that the present invention, including the pressure control system 20 and the piston extension 22, may be configured as appropriate for the application. The embodiments and example described above are to be considered in all respects only as illustrative and not restrictive.

## Claims

WHAT IS CLAIMED IS:

1. A pressure control system for an injector, the pressure control system comprising:

a first member operably associated with a drive mechanism of the injector, the first member comprising a front end;

a second member operably associated with the first member, the second member comprising a rear surface and a front end adapted to be connected to a plunger of a syringe mounted on the injector; and

a spring member disposed between the front end of the first member and the rear surface of the second member, the spring member operable to adjust for pressure increases in the syringe.

2. The pressure control system of Claim 1 wherein the front end of the second member comprises a threaded section for connection to mating threads of the syringe plunger.

3. The pressure control system of Claim 1 wherein the spring member comprises a urethane spring.

4. The pressure control system of Claim 1 wherein the first member comprises at least one wall member extending from the front end thereof and the second member comprises at least one flange member extending therefrom, the at least one flange member of the second member operably associated with the at least one wall member of the first member.

5. The pressure control system of Claim 4, further comprising a ring disposed between the at least one wall member of the first member and the at least one flange member of the second member.

6. The pressure control system of Claim 5 wherein the ring is formed of foam.

7. The pressure control system of Claim 1 wherein the first member, the second member and the spring member each define a bore disposed therein.

8. The pressure control system of Claim 7, further comprising a fastener member disposed through the bores defined in the first member, the second member and the spring member for fastening the members together.

9. The pressure control system of Claim 8 wherein the fastener member comprises a bolt.

10. The pressure control system of Claim 7, further comprising a plug member disposed within the bore of the second member, the plug member operable to stiffen the second member.

11. A pressure control system of Claim 1 wherein the first member further comprises a rear end, the rear end adapted to be removably connected to a piston of the injector.

12. The pressure control system of Claim 11 wherein the rear end of the first member comprises an attachment member for connecting the first member to the piston.

13. The pressure control system of Claim 11, further comprising a plunger member at least partially disposed in a bore formed in the first member, the plunger member operable to engage the piston of the injector to retain the first member thereon.

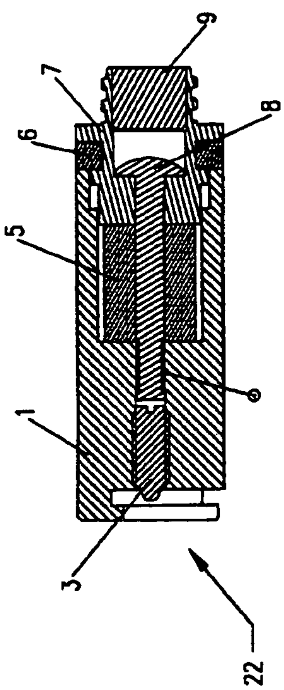



FIG.2

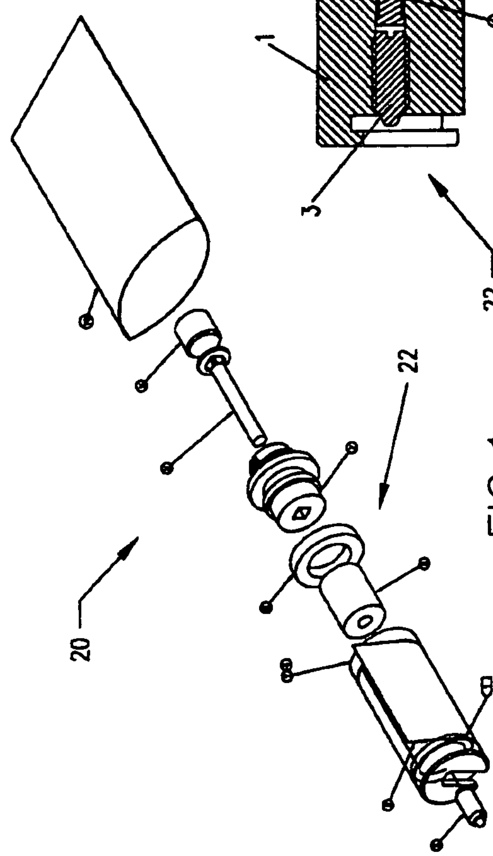
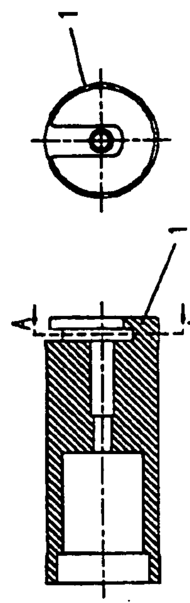



FIG.1




SECTION B-B

FIG.3A

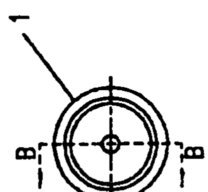
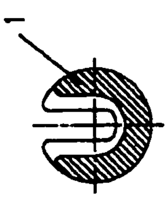



FIG.3B




SECTION A-A

FIG.3C

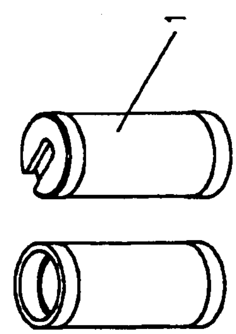
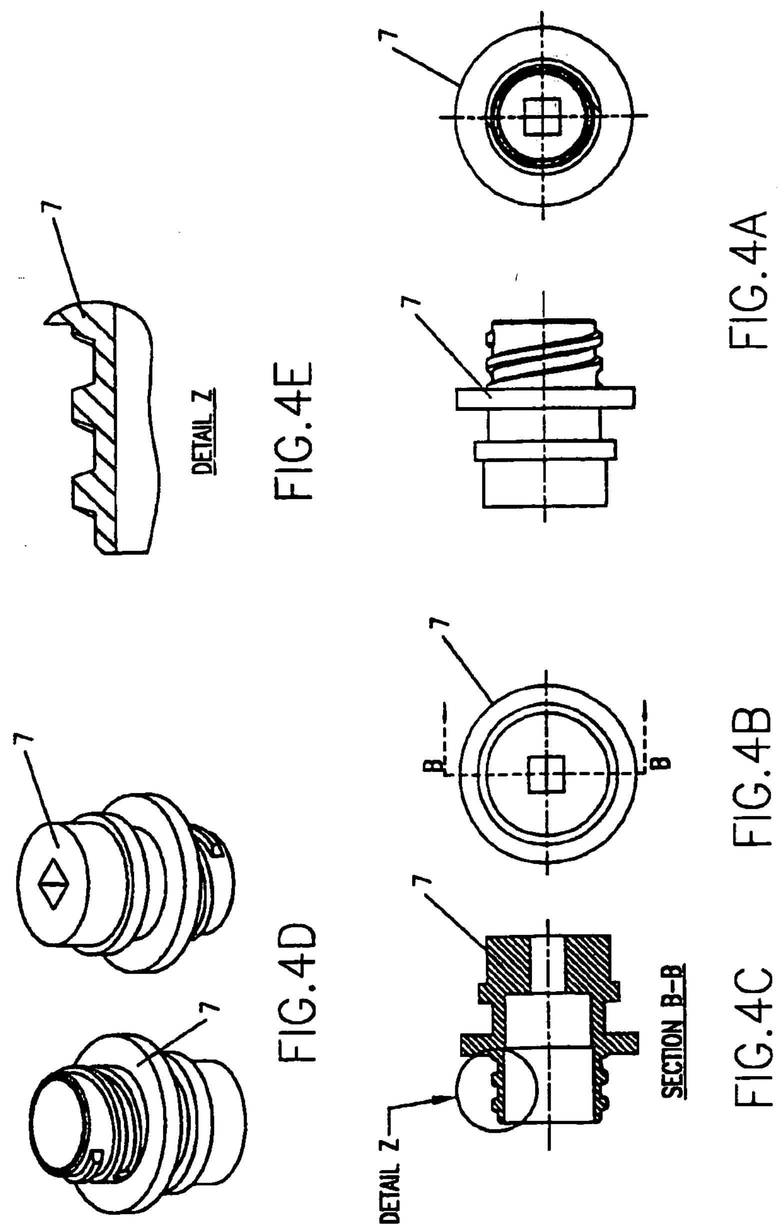



FIG.3D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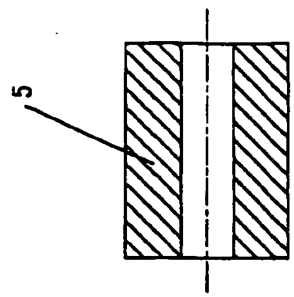
DETAIL Z
FIG.4E
FIG.4A
FIG.4D
B
B
FIG.4B
SECTION B-B
DETAIL Z
FIG.4C




SECTION A-A

FIG.5B

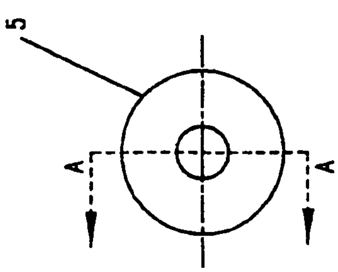



FIG.5A

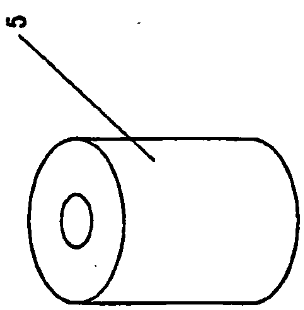
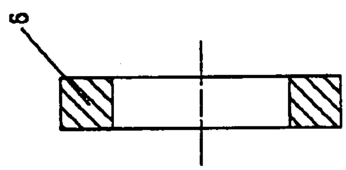



FIG.5C




SECTION A–A

FIG.6B

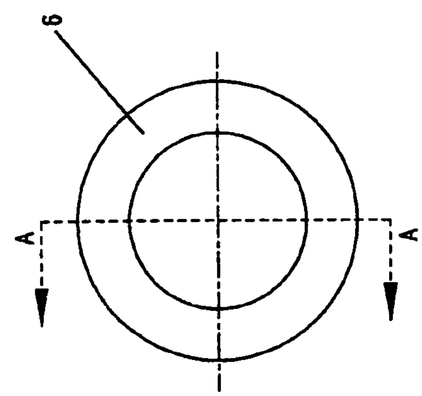



FIG.6A

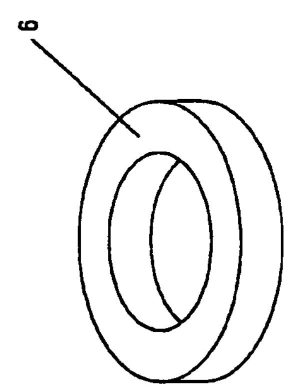



FIG.6C

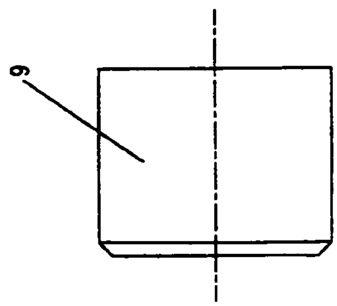



FIG.7B

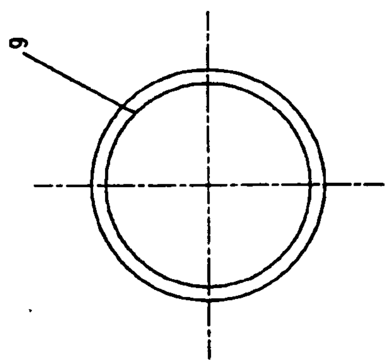



FIG.7A

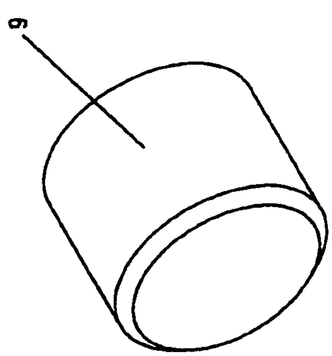



FIG.7C

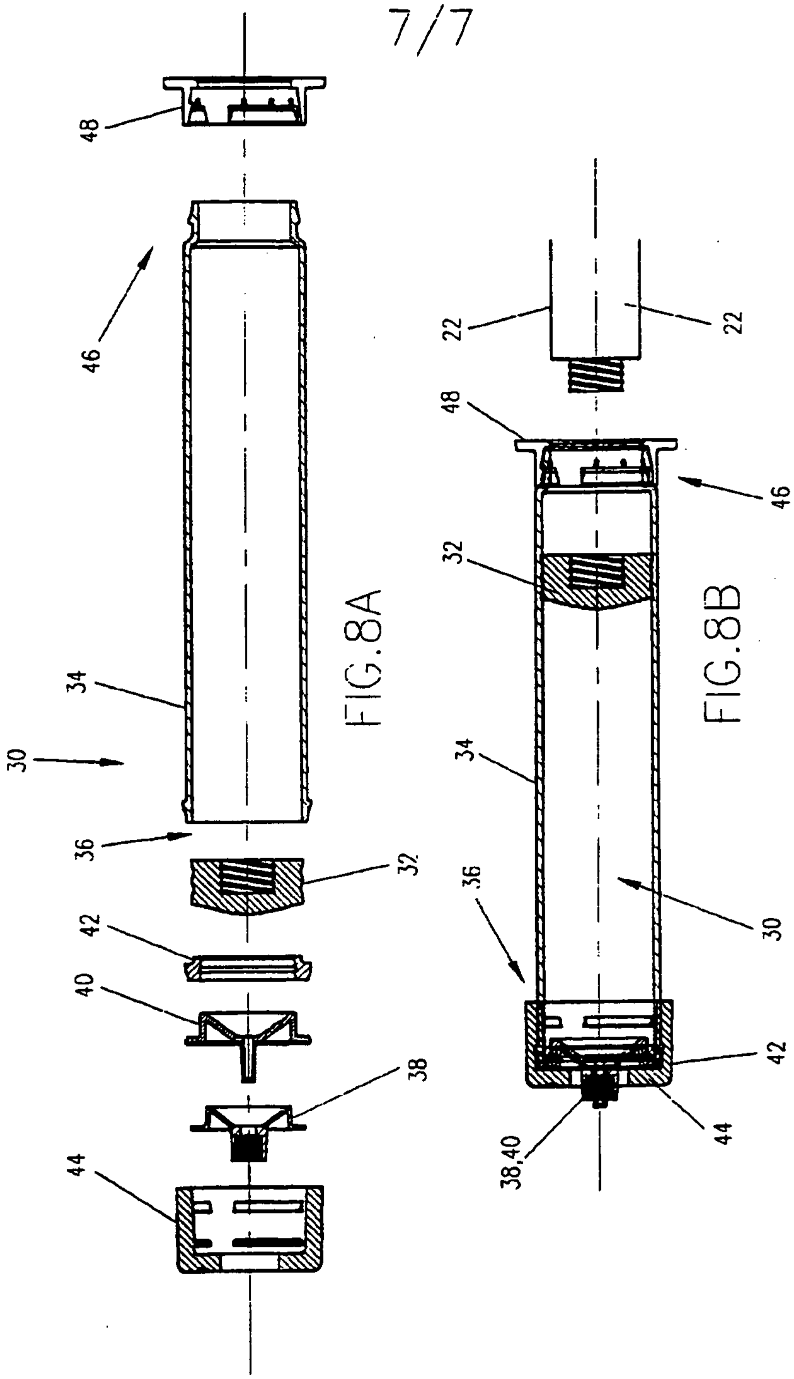



FIG.8A

FIG.8B

# INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
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| A | DE 44 28 467 A (ENK) 15 February 1996 (1996-02-15) column 9, line 31 -column 10, line 15 figures 1,2 | 1 |

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☒ Patent family members are listed in annex.

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| 22 December 1999 | 11/01/2000 |

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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| Patent document cited in search report | | Publication date | Patent family member(s) | | Publication date |
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